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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,811	07/10/2007	Jean-Guy Lehoux	2003390-0032 (ROBIC 01236	4922
24280 7590 09/28/2011 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER BLAND, LAYLA D	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 09/28/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/584,811	LEHOUX ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	LAYLA BLAND	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 1,3-6,9,11 and 13-19 is/are pending in the application.
- 5a) Of the above claim(s) 13-19 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1, 3-6, 9, 11 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/06)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

This Office Action is in response to Applicant's request for continued examination (RCE) filed July 27, 2011, and amendment and response to the Final Office Action (mailed January 27, 2011), filed July 27, 2011 wherein claim 1 is amended and claims 2, 7-8, and 12 are canceled.

Claims 1, 3-6, 9, and 11 are examined on the merits herein.

In view of the cancellation of claims 2 and 10, all rejections made with respect to those claims in the previous office action are withdrawn.

The rejection of claim 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn. As noted by Applicant, the rejection of claim 11 was erroneous and claim 10 was intended to be rejected. Claim 10 is now cancelled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 depends from claim 1 and limits "said inorganic or organic salt." Claim 1 requires at least two salts. It is unclear whether the claim 5 limitation applies to both of the salts recited in claim 1 or only one of the salts recited in claim 1.

The following rejection is modified and maintained:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan (CN 1364815A, August 21 2002, PTO-1449) in view of Mallon et al. (US 5,733,462, March 31, 2998, of record) and Singla et al. (Journal of Pharmacy and Pharmacology 2001, 53:1047-1067, of record).

Tan teaches methods for precipitating chitosan. Chitosan is dissolved in aqueous acid and then salted out. Acids to be used include acetic acid or hydrochloric acid and salts to be used include sodium sulfate, potassium sulfate, ammonium sulfate [claims 4-6].

Tan does not teach salting out using a combination of a kosmotropic salt a chaotropic salt.

Mallon teaches methods for precipitating cationic polymers using salt solutions [see abstract]. The process comprises mixing, in any order, water, at least one cationic water-soluble polymer, an effective amount of kosmotropic salt, and an effective amount of chaotropic salt to form an aqueous composition comprising at least one precipitated cationic water-soluble polymer [column 5, lines 14-32]. Water-soluble cationic polymers are precipitated more effectively by a combination of chaotropic and kosmotropic salts than by either salt alone [column 8, lines 27-42], and the total salt level useful for precipitating a cationic polymer may be lower when a mixture of chaotropic and kosmotropic salts are used compared to using a kosmotropic salt alone [column 22,

lines 62-67]. Exemplified salt combinations include ammonium sulfate and sodium thiocyanate or sodium sulfate and sodium thiocyanate [Figures 1 and 2]. Other chaotropic salts include perchlorate, chlorate, bromate, iodide, nitrate, and bromide [column 3, lines 21-32].

Singla teaches that chitosan is a cationic polymer which is soluble at acidic pH [page 1049, Table 3]. A high electrolyte concentration results in a salting-out effect leading to precipitation of chitosan from the solution [page 1049, first full paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the precipitation or salting-out of chitosan using a combination of a kosmotropic and a chaotropic salt. Salting-out with kosmotropic salts such as sulfates is known, as taught by Tan and Singla. Mallon teaches that precipitation of cationic polymers is more efficient using the combination of a kosmotropic and a chaotropic salt than either alone. The skilled artisan would precipitate chitosan using a combination of salts because Mallon teaches that the total salt level using a combination of salts may be lower than if a single salt is used. Mallon's examples include ammonium sulfate and sodium thiocyanate or sodium sulfate and sodium thiocyanate and precipitation of chitosan using sodium sulfate alone is known, as taught by Tan. The skilled artisan would expect that the combination of ammonium sulfate and sodium thiocyanate or sodium sulfate and sodium thiocyanate would effectively precipitate chitosan because sodium sulfate is already known for that purpose and Mallon teaches that addition of another salt such as sodium thiocyanate

would give a more effective precipitation. Mallon also teaches other chaotropic salts which may be used.

### ***Response to Arguments***

Applicant argues that Mallon does not mention chitosan, exemplifies polymers which are structurally different from chitosan, and does not refer to polymers for human or animal use. This argument has been carefully considered but is not persuasive. The examiner agrees that Mallon's examples are different from chitosan, but Mallon's broad teaching is directed to cationic, water soluble polymers. Chitosan in acidic solution, as taught by Tan and Singla, is a cationic, water soluble polymer. Salting-out of chitosan using kosmotropic salts is known. Mallon teaches that the total salt level used for precipitating a cationic polymer is lower when the mixture of salts is used as compared to using a kosmotropic salt alone. Thus, the skilled artisan would understand that Mallon's process is applicable to those cationic polymers which can be precipitated using kosmotropic salts, and that Mallon's process is an improvement because a lower salt level can be used.

Applicant argues that Tan did not disclose data to support the recited high purity and yield, so Tan's disclosure is not an enabling source of methodology. This argument is not persuasive because Tan does teach the amount of chitosan starting material and the amount of chitosan product (see Examples), which can be used to calculate yield. Tan does not disclose how the purity was determined, but chitosan has been prepared and used for pharmaceutical applications for years, as disclosed by Singla. Pharmaceutical products must be analyzed for purity, so the skilled artisan

would expect that techniques for analyzing chitosans are known. MPEP 2121 states that a prior art reference is presumed to be operable, and that the burden is on applicant to provide facts rebutting the presumption of operability. Applicant has noted that Tan did not disclose data or analytical techniques, but these are conventional in the art and Applicant has not provided any facts which would rebut the presumption that Tan's process is operable.

For these reasons, the rejection is maintained.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/  
Primary Examiner, Art Unit 1623